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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,006	09/10/1999	DOLORES M. BERGER	P-4762	3611

7590 09/26/2002

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/26/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/394,006

Applicant(s)

BERGER ET AL.

Examiner

BJ Forman

Art Unit

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 September 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 17 September 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached Continuation of Advisory Action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-4 6-8 10 12-17.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

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Continuation of Advisory Action

1. This action is in response to papers filed 17 September 2002 in Paper No. 21 in which Applicant requested reconsideration of the rejections in the Office Action of Paper No. 18. All of the arguments have been thoroughly reviewed and are discussed below. The arguments are not found persuasive for the reasons stated below. The previous rejections of Paper No. 18 are maintained.

Claims 1-4, 6-8, 10 and 12-17 are under prosecution.

Response to Arguments

2. Applicant argues that Essenfeld et al do not disclose the instant invention because their fixative solution consists of an alcohol and a ketone while the instant invention does not require both. The argument has been considered but is not found persuasive because the claims are drawn to a composition for stabilizing the nucleic acids of at least one cell in a specimen, the composition comprising a first substance comprising at least one alcohol or ketone. The open claim language "comprising" encompasses the alcohol and ketone of Essenfeld et al. Therefore, the claimed composition encompasses the composition of Essenfeld et al. and hence, Essenfeld disclose the composition as claimed.

Applicant argues that Essenfeld et al include DMSA on their list of surfactants and do not provide any teaching utilizing surfactant at 50%. The argument has been considered but it is not understood how this argument relates to the claims or the previous rejection under 102 (e) because Claims 13-16, 18, 25-26, 31 and 35 do not recite DMSO at 50%. Therefore, the argument is deemed moot because it does not address the claims or the rejection.

However, as the argument relates to the rejection under 103, the argument is not found

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persuasive for the reasons stated in the Office Action i.e. the courts have stated that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation (*In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235). Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Essenfeld et al using routine experimentation to derive a composition comprising 50% DMSO for the obvious benefits of optimizing experimental conditions to thereby maximize experimental results.

Applicant argues that Essenfeld et al do not teach or suggest using their solution with specimens other than tissue. The argument has been considered but is not found persuasive because the claims are drawn to a composition for stabilizing the nucleic acids of at least one cell in a sample. Essenfeld et al clearly teach stabilizing nucleic acids in tissue samples (Example 1, Column 16, lines 23-28) and they clearly teach the tissue samples contain cells (Column 5, lines 50-55). Therefore, Essenfeld et al disclose the method as claimed.

3. Regarding the rejections over Essenfeld et al in view of Evinger-Hodges et al, Applicant states that Evinger-Hodges is not a properly cited reference. Because Applicant has not pointed to an error in the citation, the argument is deemed moot.

Applicant argues that the examiner has made numerous inappropriate extrapolations with respect to time and temperature conditions because 72-96 is not the same as 3 hours. The argument has been considered but is not found persuasive for the reasons stated in the Office Action i.e. the courts have stated that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation (*In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235). Therefore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Essenfeld et al and Evinger-Hodges et al using routine

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experimentation to derive optimal incubation time and temperature for the obvious benefits of optimizing experimental conditions to thereby maximize experimental results.

4. Regarding the rejections over Rogers, Applicant argues that the examiner has made numerous improper assumptions that Rogers teaches or renders obvious the claimed invention because no concentrations are described in the Rogers reference which contrasts with the instant invention which sets forth specific concentrations. The argument has been considered but is not found persuasive because Rogers et al do teach specific concentrations as pointed to in the Office Action i.e. 1:4 (Column 5, lines 62-66). Additionally, it is noted that the claims are rejected as obvious over Rogers under 35 U.S.C. 103 and as stated in the Office Action, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the exact concentrations of Rogers using routine experimentation to thereby derive an optimal composition for stabilizing cells because the skilled practitioner in the art would have been motivated to optimize the composition to thereby maximize experimental results.

Applicant argues that the examiner's comments about evaporation and spillage presume facts not proven or easily demonstrable. The argument has been considered but is not found persuasive for the reasons stated in the Office Action i.e. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the exact concentrations of Rogers using routine experimentation to thereby derive an optimal composition for stabilizing cells because the skilled practitioner in the art would have been motivated to optimize the composition to thereby maximize experimental results. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

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Conclusion


5. The examiner's Art Unit has changed from 1655 to 1634. Please address future correspondence to Art Unit 1634.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
September 25, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600